

**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OKLAHOMA**

STATE OF OKLAHOMA, *et al.*)

)

Plaintiffs,)

)

v.)

Case No. 4:05-cv-00329-GKF-PJC

)

TYSON FOODS, INC., *et al.*)

)

Defendants.)

)

**DEFENDANTS' OPPOSITION TO PLAINTIFFS' MOTION FOR PROTECTIVE
ORDER REGARDING THE SCIENTIFIC PEER REVIEW PROCESS (DKT. NO. 2034)**

Defendants respectfully submit this brief in opposition to Plaintiffs' motion for a protective order shielding them from any obligation to produce materials related to manuscripts submitted for peer review by their expert witnesses. *See* Dkt. No. 2034 (May 11, 2009) ("Motion for a Protective Order" or "Pls. Mot."). This Opposition also supports Defendants' Motion to Compel production of those same materials. *See* Dkt. No. 2000 (Apr. 24, 2009) ("Motion to Compel" or "Dfts. Mot."). As explained in the Motion to Compel, and contrary to Plaintiffs' suggestion, Defendants are not seeking production of any materials from journals or scientists participating in any peer review process. Rather, Plaintiffs are withholding, without basis in law, draft articles, e-mails, correspondence and memos that are in the possession of Plaintiffs' attorneys and their experts.

Plaintiffs are engaged in a coordinated effort to generate peer reviewed journal articles to support the scientific case they plan to present at trial. *See* Dfts. Mot. at 3-4 & Exs. 2, 3. Specifically, several of their expert witnesses have prepared manuscripts that they have or will submit to scientific journals for peer review and possibly publication. As part of that process, Plaintiffs and their expert witnesses generated notes, drafts, and correspondence. In fact, Plaintiffs have previously produced examples of such materials, but now refuse to continue to do so.¹ Indeed, rather than simply oppose Defendants' Motion to Compel, Plaintiffs now seek an order alleviating them of any responsibility to produce in a timely manner any of these materials

¹ As noted in the Motion to Compel, the parties previously agreed that Plaintiffs would inform Defendants within 48 hours of the submission of a manuscript for peer review and would produce relevant background materials except materials that identified the journal to which the manuscript was submitted. *See* Ex. 1 (Feb. 27, 2009 Ltr. from J. Jorgensen to L. Bullock). In light of that agreement and the fact that Defendants have already provided the omitted data to the currently-relevant journals, Defendants approached Plaintiffs and asked that the parties dismiss these cross-motions. Plaintiffs refused, indicating that they may submit other materials to journals in this case and would like to keep those documents concealed. *See* Ex. 2 (May 21, 2009 Email from J. Jorgensen to L. Bullock).

and sharply curtailing their eventual, untimely production so that the Court is not alerted to any negative comments that the peer reviewers may provide. *See* Motion for a Protective Order at 19. Plaintiffs' submission makes clear that Plaintiffs have no appropriate legal basis to resist production of these highly relevant materials.

A. Materials Related to Manuscripts Submitted to Scientific Journals By Plaintiffs' Experts Are Discoverable Under Rule 26(b)

As demonstrated in the Motion to Compel, Federal Rule of Civil Procedure 26(b) entitles a party in litigation to seek discovery into any "relevant" issue, which includes any information reasonably calculated to lead to the discovery of admissible evidence. *See* Dfts. Mot. at 7-8. The materials that Plaintiffs are withholding fall squarely within this rule, as they are relevant to the testimony that Plaintiffs' experts will offer at trial. *See id.* at 8-9. Plaintiffs do not deny that they possess these materials, nor do they deny that these documents are the subject of discovery that Defendants properly served *long before the discovery cutoff* and which Defendants have sought to enforce. Nor do Plaintiffs contest that the materials they have withheld (in some cases for many months) fall squarely within the universe of materials discoverable pursuant to Rule 26(b)'s "relevancy" standard. *See* Dfts. Mot. at 6-9.

Instead, Plaintiffs argue that Rule 26(b) requires a "balancing of the interests." Pls. Mot. at 9-10. But Plaintiffs mistake the protections afforded to non-parties against invasive discovery with the rules applicable to party discovery. Specifically, Plaintiffs rely exclusively on authorities regarding discovery requests made to non-party strangers to the litigation. *See* Pls. Mot. at 9 (citing *Farnsworth v. Proctor & Gamble, Co.*, 758 F.2d 1545, 1547 (11th Cir. 1985) (rejecting discovery seeking to require non-party Center for Disease Control to disclose the names of women who participated in a study on toxic shock syndrome), and *Plough, Inc. v. National Academy of Sciences*, 530 A.2d 1152, 1160 (D.C. 1987) (declining to require National

Academy to disclose materials underlying a study being used against Plough in other litigation)); *see also id.* at 13-14 (citing *In re Bextra & Celebrex Marketing Sales Practices & Prods. Liability Litig.*, 249 F.R.D. 8 (D. Mass. 2008), and *In re Bextra & Celebrex Marketing Sales Practices & Prods. Liability Litig.*, 2008 WL 4345158 (N.D. Ill. March 14, 2008), both regarding discovery demands to non-party journals). These cases are immaterial because the discovery Defendants seek to compel was not directed to a non-party but rather was directed to Plaintiffs.

Plaintiffs gloss over the fact that the only materials Defendants have sought are in Plaintiffs' own possession.² *See* Dfts. Mot. at 9-10. Specifically, Defendants requested:

[A]ll correspondence between Plaintiffs, Plaintiffs' Experts, Plaintiffs' Attorneys, or any person or agent acting on Plaintiffs' behalf and any publication, association, journal, or other entity regarding the submission for peer review and/or publication as an article, poster, abstract, or in any format of the scientific opinions provided or to be provided by [Plaintiffs' retained experts] in this Lawsuit, [and],

all materials including but not limited to any drafts or versions of any article, poster, abstract, or material in any other format, with all supporting data, figures, tables, illustrations, references, and appendices, submitted or made available to any publication, association, journal, or other entity for peer review and/or publication regarding the scientific opinions provided or to be provided by [Plaintiffs' retained experts] in this Lawsuit.

Dfts. Mot. Ex. 5 at 2-3, 5-7. Plaintiffs' "balancing test" has no application to discovery requests directed from one party to another.

Rather, the appropriate test is whether the materials are relevant to the points at issue in the litigation, which these materials indisputably are. Plaintiffs concede that these materials are relevant to impeachment of their expert witnesses. *See* Pls. Mot. at 13. Indeed, substantive

² Defendants did not serve any discovery on the journals or otherwise seek materials from them, nor do Defendants have any intention of ever doing so. As Plaintiffs point out, Defendants' letters to both AEM and JAWRA did request that they preserve relevant materials. *See* Pls. Mot. at 3. Far from some effort to "intimidate," Defendants' request was perfectly reasonable in view of Plaintiffs' refusal to produce relevant and discoverable materials and the covert manner in which Plaintiffs have undertaken this effort. Lest there be any doubt on this point, Defendants will not seek any discovery from any non-party journal.

differences between an expert's report submitted in litigation and a manuscript submitted for publication raise serious issues regarding the reliability of the expert's analyses and the corresponding weight that should be given to the peer review process under *Daubert* and its progeny. *See, e.g., In re Rezulin Prods. Liab. Litig.*, 369 F. Supp. 2d 398, 423 (S.D.N.Y. 2005) (discrediting peer review of an "edited version of Dr. Smith's report, which used more tentative language and which he published in a toxicology journal at the suggestion of a member of its editorial board who also is a paid consultant for plaintiffs in this litigation"). Here, as Defendants' Motion to Compel demonstrated, Plaintiffs' experts' submissions to the journals have differed in a number of material respects from their submissions and testimony in court. *See Dfts. Mot.* at 4, 12-14.

But that is not the extent of the relevance of these materials. Rather, they go first to whether Plaintiffs' experts' proposed opinions are even admissible under Rule 702. Plaintiffs' efforts to secure peer review for their litigation work is relevant to the Court's *Daubert* analysis. Federal courts have consistently recognized that expert opinions developed in litigation merit close scrutiny lest they reflect a lawyer's pre-determined conclusions rather than impartial scientific scrutiny.³ *See Norris v. Baxter Healthcare Corp.*, 397 F.3d 878, 886 (10th Cir. 2005); *Daubert v. Merrell Dow Pharm., Inc.*, 43 F.3d 1311, 1317-18 (9th Cir. 1995) ("[A] scientist's normal workplace is the lab or the field, not the courtroom or the lawyer's office."). Indeed,

³ Plaintiffs take umbrage at Defendants' suggestion that Plaintiffs' counsel played any role in the submission of these manuscripts, and assert that "[i]n truth, Dr. Harwood herself made the decision to submit the manuscript to AEM and no lawyer pre-determined the results of her work." *Pls. Mot.* at 3. However, the evidence shows otherwise, as Dr. Harwood and her colleagues' submission were closely monitored and the draft was approved by Plaintiffs' counsel. *See Ex. 4* (e-mails among Plaintiffs' experts and counsel regarding preparation and approval of manuscript). Defendants' expert Dr. Myoda acknowledged this concern when he observed that, under Plaintiffs' direction, Dr. Harwood was not meeting her own usual standards. *See Pls. Mot. Ex. 5* at 4.

hired expert testimony can “turn[] scientific analysis on its head[,] ... reason[ing] from an end result in order to hypothesize what needed to be known but what was not.” *Mitchell v. Gencorp, Inc.*, 165 F.3d 778, 783 (10th Cir. 1999) (quotations omitted); *see also Cabrera v. Cordis Corp.*, 134 F.3d 1418, 1420-21 (9th Cir. 1998); *Sorenson v. Shaklee Corp.*, 31 F.3d 638, 649 (8th Cir. 1994). *Daubert* does not demand inquiry into every peer reviewed article, *cf.* Pls. Mot. at 13, but it certainly supports scrutiny of the submission of an expert’s report during litigation.

Courts have excluded peer reviewed expert testimony where the expert failed to disclose the context in which their work was undertaken. *See, e.g., National Bank of Commerce (of El Dorado, Ark.) v. Dow Chem. Co.*, 965 F. Supp. 1490, 1516 (E.D. Ark. 1996) (“Plaintiffs claim Dr. Sherman’s articles were peer reviewed. But her potential bias because of her direct involvement in litigation in the four cases on which she reported was not disclosed in her articles. Nor did she disclose the opinion of experts attributing the birth defects to genetic causes. And the opinions she expressed in the articles do not go to the same extent as the opinions she would put before the jury. So the court discounts the value of any peer review that might have occurred with respect to those articles”); *id.* at 1535 (“[With respect to a separate study, i]t is important to also note, however, that Dr. Sherman did not disclose in either of her articles that the cases she was reporting on were all involved in litigation, in which she had been hired as an expert.”); *Black v. Rhone-Poulenc, Inc.*, 19 F. Supp. 2d 592, 600 (S.D. W. Va. 1998) (discrediting peer review and publication of the work because the authors presented a variation of the methodology and failed to disclose, among other things, “the poor record keeping which occurred, and his disclosure to participants of Neely & Hunter’s sponsorship of the study”). Accordingly, the Court should reject the complaint that Defendants have alerted journals to the litigation context; such disclosure is a required part of genuine peer review.

Here, Plaintiffs' own exhibits discuss the importance of transparency in the funding of scientific research, *see* Pls. Mot. Ex. 9a at 23-24, Ex. 9b at 17-18, and JAWRA's own rules require the disclosure of "any interests or affiliations that could be perceived as influencing the objectivity of their writings." Dfts. Mot. at 11. However, the submitted manuscript gives no hint that the research was paid for by Plaintiffs' attorneys, and that it is in large part reproduced wholesale from a report submitted as part of this litigation. Whether those disclosures were made is highly relevant, but Plaintiffs refuse to produce any materials regarding that fact and protest that the Court should not allow Defendants to inform the journals of this omitted information.⁴

The materials Defendants have requested from Plaintiffs are classic non-privileged documents that are clearly relevant to Plaintiffs' experts' work in this litigation. *See* Defts.' Mot. at 6-9. For that very reason Plaintiffs have previously produced the very same material with respect to their submission of the Harwood manuscript to *AEM*. *See* Mot. at 9-10. Plaintiffs cannot now renege on that previously recognized discovery obligation and refuse to produce these relevant materials.

B. Plaintiffs' Claims Of Confidentiality Are Unsupported In Law Or Fact

Plaintiffs wrap themselves in the cloak of the "scientific peer review process," which, they argue, must be kept "confidential" and unsullied by lawyers' hands. Pls. Mot. at 4-8. But the fact remains that it was Plaintiffs, not Defendants, who involved these non-party journals; Plaintiffs, not Defendants, who elected to omit material information from their submissions; and

⁴ While Plaintiffs profess great indignation at the suggestion that the prospect of remuneration could influence an experts' or an attorneys' views, they also note that Defendants' experts are "well-paid." Pls. Mot. at 5-6. They thus recognize what JAWRA and most other scientific journals recognize—that the source of funding matters. The fact is that whether or not it actually does have an impact, the source of funding is relevant and should be disclosed. Moreover, this underscores why if a journal is to review science undertaken in litigation, it should be allowed to receive submissions from both sides or not at all.

Plaintiffs, not Defendants, who will attempt to use the results of these peer review submissions as evidence at trial in support of their case. Defendants would welcome an order barring either side from bolstering their case-in-chief with the results of peer review solicited during the litigation. However, to the extent that Plaintiffs plan on introducing such results in this litigation, Defendants have every interest and right in ensuring that that peer review is fully informed.

Plaintiffs have not substantiated any basis for their claim of confidentiality. They admit that the materials in their possession are not legally privileged. *See* Pls. Mot. at 10. Instead, they argue that the materials are “confidential” and attempt to justify their refusal to disclose them on the basis that disclosure would injure the peer review process. *Id.* at 9-12. That argument fails for several reasons. *First*, Plaintiffs are impermissibly attempting to assert the confidentiality rights of unrelated third parties. To the extent that there is any confidence to keep at all, that confidence belongs not to Plaintiffs but to the journals. *See Laxalt v. McClatchy*, 809 F.2d 885, 891 (D.C. Cir. 1987) (rejecting objection to discovery invoking the rights of absent third parties); *Diamantis v. Milton Bradley Co.*, 772 F.2d 3, 4-5 (1st Cir. 1985) (same). Indeed, all of the cases upon which Plaintiffs rely address a journal’s or other non-party scientific entity’s efforts to resist discovery. *See supra* at 3. Here, the journals have not filed any papers or otherwise attempted to prevent Defendants from seeking the materials in Plaintiffs’ possession, and Plaintiffs lack standing to do so for them. *See Laxalt*, 809 F.2d at 891; *Diamantis*, 772 F.2d at 4-5.

Second, the materials that Defendants seek are not “confidential” as Plaintiffs use that term. Pls. Mot. at 9. Rule 26(c)(1)(G) contemplates “trade secret[s,] confidential research, development, or commercial information,” Fed. R. Civ. P. 26(c)(1)(G), in short, intellectual property whose “only value consists in their being kept private,” *Level 3 Communications v.*

Limelight Networks, Inc., ___ F. Supp. 2d ___, 2009 WL 1208990, at *8 (E.D. Va. 2009)

(quotations omitted). The materials here, far from being a commercial secret, were developed in preparation for submission to a third party and ultimately for publication. Moreover, while Plaintiffs assert a need to protect the inner workings of the peer review process, *see* Pls. Mot. at 10-13, they nowhere explain how release of their own notes, drafts, and correspondence, or materials disclosed back to them from a journal, would upset those inner workings. *See supra* at 3-4. Nor can they. No rule or regulation allows a party to refuse to produce its own experts' materials simply because the end product was sent to a journal. Were that the rule, courts would see a substantial rise in journal submissions. Nor can Plaintiffs claim that the peer review process will be upset by the disclosure of materials that the journals themselves have already disclosed. They have not identified any "chilling effect on the free flow of information" between journals and peer reviewers that will result from production to Defendants of what has already been disclosed to Plaintiffs. Pls. Mot. at 12. In fact, Plaintiffs have not demonstrated that they even possess any documents that could undermine the peer review process. Plaintiffs have not produced any privilege log identifying any withheld materials. They have not demonstrated, for example, a need to redact particular documents to conceal the identity of peer reviewers.⁵ Instead, they seek a sweeping injunction against any discovery obligation whatsoever, but for the final manuscript and final outcome of the peer review. *See* Pls. Mot. at 19. Plaintiffs' request to curtail discovery lacks any basis in law.

⁵ Plaintiffs mischaracterize Tyson's prior request for the identities of putative peer reviewers. *See* Pls. Mot. at 4. Tyson never sought to discover, nor would Tyson ever seek to discover, the identities of the actual peer reviewers. Rather, Tyson asked Plaintiffs to disclose the identities of the individuals who Professor Harwood recommended to AEM as potential reviewers. This was relevant to confirm that Dr. Harwood had not *recommended* individuals associated with this case. At her deposition Dr. Harwood agreed to produce these names, which she could not recall at the time, but Plaintiffs subsequently reneged on this obligation, only producing the names after Defendants moved to compel. *See* Dkt. No. 1851 at 4-5.

C. Plaintiffs' Demands For Secrecy Contradict Sound Scientific Standards And The Full and Open Discussion Of Scientific Evidence

Plaintiffs' fundamental objection is that, if Defendants are allowed access to the documents in Plaintiffs' possession, Defendants may write to the journals to present data and expert opinions that Plaintiffs omitted from their submissions. *See* Pls.' Mot. at 2-8, 12, 15-19; *see also* Dfts. Mot. at 9-14. Plaintiffs also fear that Defendants will bring to the Court's attention any comments and criticisms that the peer reviewers provide. To that end, Plaintiffs argue, ironically, that requiring disclosure would "chill the free flow of information." Pls. Mot. at 8; *id.* Ex. 4 ¶ 10. But the disclosures that Plaintiffs oppose are not only positive, they are what the scientific process and the law require.

First, the submission of relevant data and expert analysis to scientific journals is an affirmative good that Courts recognize should be protected and encouraged. The scientific process demands that all data and expert analysis relevant to an issue be presented and evaluated by the scientific community, not that one side of the story be suppressed. Plaintiffs complain of Defendants' "one-sided critique," Pls. Mot. at 3, but ask the Court to shield their own self-serving and one-sided correspondence. Precisely because litigation is adversarial, a journal is best off if it hears from both sides. One-sided submissions deprive the scientists who review their work of available data, expert opinions, and context that are highly relevant to the reliability of the opinions expressed in the articles. Depriving the scientific process of relevant information is likely to produce a biased (and unreliable) result. Thus, peer review under these circumstances is of limited worth.

Defendants' submissions to any journals constitute free and informed speech that benefits scientific analysis. *See Thornhill v. Alabama*, 310 U.S. 88, 102 (1940) ("Freedom of discussion, if it would fulfill its historic function in this nation, must embrace all issues about which

information is needed or appropriate....”); *Hustler Magazine v. Falwell*, 485 U.S. 46, 50 (1988) (“At the heart of the First Amendment is the recognition of the fundamental importance of the free flow of ideas and opinions on matters of public interest and concern.”). It is particularly important that competing theories and data are openly examined in the scientific process. More than simply protected speech under the First Amendment, Defendants’ correspondence is in fact favored by the courts as speech benefiting the scientific community through the disclosure of additional information for the peer review publication to consider in determining the soundness of the experts’ work. *See Whitney v. California*, 274 U.S. 357, 377 (1926) (Brandeis, J., concurring), *overruled by Brandenburg v. Ohio*, 395 U.S. 444 (1969) (“If there be time to expose through discussion the falsehood and fallacies, to avert the evil by the processes of education, the remedy to be applied is more speech, not enforced silence.”). For these reasons, “the First Amendment protects scientific expression and debate just as it protects political and artistic expression.” *Bd. of Tr. of Leland Stanford Junior Univ. v. Sullivan*, 773 F. Supp. 472, 474 (D.D.C. 1991); *see generally Miller v. California*, 413 U.S. 15, 34 (1973). Plaintiffs know full well that a request to impose a prior restraint on Defendants preventing them from speaking to scientific journals would violate the First Amendment. Instead, Plaintiffs attempt to do through the back door by shirking their discovery obligations that which they cannot achieve through the front door. This effort should be rejected.

Similarly, ensuring that the journals have had access to all of the relevant data and analysis supports this Court’s *Daubert* analysis. *See McMillan v. Togus Reg’l Office, Dep’t of Vet. Affairs*, 294 F. Supp. 2d 305, 317 (“Sound scientific studies are essential to our legal foundations as well as to individual justice.”) (citing Breyer, J., *Introduction to Fed. Judicial Ctr., Reference Manual on Scientific Evidence* (2d ed. 2000)). Plaintiffs have selected the data and

opinions they want the peer reviewers to see, but they object to Defendants presenting the rest of the story. Allowing lawyers to make decisions about what data scientists should be allowed to see (and what should be withheld) is antithetical to *Daubert*. “[T]he examination of a scientific study by a cadre of lawyers is not the same as its examination by others trained in the field of science or medicine.” *Perry v. United States*, 755 F.2d 888, 892 (11th Cir. 1985).

Plaintiffs contend that the “scientific peer review process” should not constitute an “adversarial process,” but rather a “straightforward scientific publication decision” based solely on the information that Plaintiffs elect to provide. Pls. Mot. at 14. A one-sided and materially deficient submission of data and expert analysis could never allow for a “straightforward scientific publication decision.” It is difficult to follow how the merits of a scientific submission “should be independently identified and resolved by the able members of the review panel,” when the review panel has been provided incomplete data and a lack of context. *Id.* at 18. But regardless, the premise of Plaintiffs’ argument on this point is wrong as a matter of science. It is well-established that “[a]s in political controversy, ‘science is, above all, an adversary process. It is an arena in which ideas do battle....’” *McMillan*, 294 F. Supp. 2d at 317 (quoting David Goodstein, *How Science Works*, in Fed. Judicial Ctr., Reference Manual on Scientific Evidence (2d ed. 2000)).

As Defendants demonstrated in their Motion, allowing Plaintiffs to avoid discovery will simply increase the burden on the Court. *See* Dfts. Mot. at 14-15. As Plaintiffs point out, “no one federal judge would have the requisite scientific background and expertise to evaluate the merits of each scientific methodology that is presented to it.” Pls. Mot. at 13. Defendants’ and Plaintiffs’ respective motions set out a number of disagreements as to the subject matter of the manuscript submitted to JAWRA. *Compare* Dfts. Mot. at 12-13, with Pls. Mot. 15-18. Yet, if

Plaintiffs have their way, the Court will have to assess Plaintiffs' experts' theories without the benefit of the views of impartial reviewers who were privy to all of the information that both sides consider to be relevant. The submission of all relevant data and analysis furthers the free exchange of ideas and the scientific process and should be encouraged.

Second, Plaintiffs concern that Defendants might inform the Court of the peer reviewers' criticisms is well founded. Indeed, that is exactly what the Court needs to carry out its gate-keeping function under *Daubert*. While peer review does not guarantee validity, it will "increase the likelihood that substantive flaws in methodology will be detected." *Daubert*, 509 U.S. at 593. But the parties must bring the flaws that the peer reviewers noted to the attention of the Court, as the Court is not independently aware of the peer reviewers' comments.

Plaintiffs' submission of an article drafted by their experts Dr. Valarie Harwood and Dr. Roger Olsen illustrates why the Court must allow normal discovery if it is to learn what "flaws in methodology" the peer reviewers detected. As discussed in *Defendants' Motion to Exclude the Testimony of Dr. Valerie J. Harwood Pursuant to Daubert v. Merrell Pharmaceuticals, Inc.*, Dkt No. 2028 ("Motion to Exclude"), Drs. Harwood and Olsen submitted a draft article to the *Journal of Applied and Environmental Microbiology* ("AEM"). That article repeated the testimony Plaintiffs' experts previously presented to this Court in the preliminary injunction hearing, wherein the experts claimed to have identified a "poultry-specific biomarker" that can be used to trace poultry litter in the environment. *Id.* at 1-5. However, the peer reviewers sharply criticized and rejected Plaintiffs' submission based on a number of grounds. AEM rejected Plaintiffs' manuscript for the first time on September 2, 2008. As AEM wrote to Dr. Harwood,

[t]he [peer] reviewers expressed a number of concerns about the manuscript. These include questions regarding the specificity of the markers for chickens...

the lack of some controls..., and the lack of sufficient data to “validate” the markers for other applications.... In addition, it was felt that the presentation of the material was inadequate, and in some cases inappropriate, for a scientific journal. For these reasons, and the reasons in the attached reviews, I am unable to accept your manuscript for publication.

Id. at 5. Plaintiffs’ experts revised the manuscript and resubmitted it on December 4, 2008, for a second round of independent peer review. AEM rejected the revised manuscript on January 23, 2009. As AEM wrote:

Two of the reviewers expressed serious concerns regarding your manuscript, as detailed in their comments. One of the most serious concerns is the potential for application of the method to other geographic regions, as other studies have shown that these biomarkers lose specificity when tests are conducted using samples from a broader geographic field regardless of the assurance made that these primers may have a broader application. Other concerns are over the lack of necessary controls and the lack of appropriate statistical analyses to support your conclusions. For these reasons, and the reasons in the attached reviews, I am unable to accept your manuscript for publication.

Ex. 7 at 1. Thus, Dr. Harwood’s biomarker theory twice failed peer review and was twice rejected for publication “for scientific reasons.” *Id.*

The peer reviewers backed up these conclusions with a long list of specific comments and criticisms.⁶ Among other comments, the peer reviewers noted that: (1) Plaintiffs’ sampling work was procedurally and statistically flawed and inadequate to support their conclusions; (2) the available data do not support Plaintiffs’ claim that this “biomarker” is unique to poultry and thus does not come from other animals; (3) Plaintiffs’ work lacked appropriate controls; (4)

⁶ Plaintiffs complain bitterly that Defendants’ submissions interfered with AEM’s peer review. *See* Pls. Mot. at 7. But, Defendants’ submissions went not to the peer reviewers but only to the AEM editors. Plaintiffs cite no evidence to support any belief that AEM shared these materials with their peer reviewers. Indeed, for all the reasons set forth in Dr. Harwood’s and Dr. Teaf’s affidavits, there is every reason to believe that AEM did not pollinate their peer reviewers’ assessment with Defendants’ submissions. *See* Pls. Mot. Ex. 4 at 2-3, Ex. 9 at 3-4. Plaintiffs’ protestations of threats and intimidation are moreover belied by Dr. Teaf’s recollection of an instance in which a journal published an article despite lawyer submissions. *See id.* at 3. Surely, the experts can be trusted to assess the information provided and act according to their best scientific judgment.

Plaintiffs' claim that their biomarker work was "validated" is scientifically incorrect; (5) Plaintiffs' regression analyses were so flawed as to be "meaningless"; and (6) the "indicator-paradigm" theory upon which Plaintiffs base their claim of a risk to human health was not developed in the context of animal manure and thus does not support Plaintiffs' allegations. *Id.* at 14-25.

Defendants quoted these comments at length in their *Motion to Exclude* to provide the Court with independent discussion of the flaws in Plaintiffs' expert work. These direct quotes from scientists in the relevant field should assist the Court in its "gatekeeping obligation to 'ensure that any and all scientific testimony or evidence admitted is not only relevant, but reliable.'" *Call v. State Indus.*, 2000 U.S. App. LEXIS 17732, 12-15 (10th Cir. 2000) (quoting *Daubert*, 509 U.S. at 589). However, Plaintiffs attempt to deprive Defendants and the Court of this information. Plaintiffs' request to narrow the scope of discovery to only the sanitized drafts Plaintiffs produce and the fact of the journal's decision should be rejected.

CONCLUSION

Plaintiffs request that they be excused from any obligation to make timely disclosure of materials in their possession, and be allowed to conceal information relevant to the points at issue in this case lacks any basis in law and must be rejected. Plaintiffs' demand that they be permitted to continue a one-sided correspondence with scientific reviewers to solicit favorable evidence to support their case, but to suppress any contrary responses runs counter to the scientific process, to the open exchange of ideas, and the rules governing discovery. Plaintiffs' Motion to Compel must be denied.

Respectfully submitted,

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